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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Soldano Ferrone

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT

PAPER NUMBER

1644

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/804,392	Applicant(s) FERRONE ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) 5-11 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3 and 4 is/are allowed.
- 6) ☒ Claim(s) 12 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application claims the benefit of the filing date of provisional U.S. Application 60455,833.

Claims 2 and 13 have been canceled.

Claims 1, 3-12 and 14-17 are currently pending.

Election/Restrictions

1. Applicant's election of Group I, claims 1-4 and 12-17, in the reply filed on February 8, 2007 is again acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5-11 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 8, 2007.

Claims 1, 3, 4, 12 and 14-17 are the subject of examination in the present Office Action.

2. In view of Applicant's amendment filed November 7, 2007, no outstanding ground of rejection has been maintained.

The following represent new grounds of rejection that necessitate this Office Action being made NON-FINAL.

Applicant's arguments with respect to claim 12 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 14- 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 14-16 are ambiguous and unclear in the recitation of “the peptide has a sequence of SEQ ID NO: X.” The phrase is written in an open format that invites the inclusion of subsequences of an undetermined size. The claims appear to be inclusive of a “sequence” of as small as two amino acid residues extracted from within the recited sequence of the peptide. It is suggested that Applicant amend the claims to recite --consists of-- in place of “has a.”

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al (J. Imm. Meth. [1986] 86:187-190; U on form PTO-892 of record) as evidenced by Tutt et al (J. Immunol. [1983] 131(6):3058-3063; V on form PTO-892 of record) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; W on form PTO-892, newly cited).and Harlow, E. et al. (Antibodies: A Laboratory Manual. [1988] pages 72-77, 92-97, 128-135, 141-157, 271,274-275, 321-323 and 626-631; X on form PTO-892, newly cited).

Stevenson teaches an ELISA assay in which soluble HLA class II antigenic material is purified from the serum of human patients using immobilized rat anti-HLA class II antibodies (paragraph bridging pages 188-189 in particular). Accordingly, the soluble HLA class II antigenic material that is immobilized on the ELISA plates is isolated and purified from the patient sera. Stevenson further teaches the detection of the immobilized HLA class II on the plates with a mouse anti-HLA class II antibody (paragraph bridging pages 188-189 in particular). While Stevenson is silent about whether the soluble HLA class II antigenic material would block the binding of anti-HLA class II antibodies to HLA class II

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bearing cells, the antigenic material would have inherently been able to bind the two anti-HLA class II antibodies taught by Stevenson and prevent their binding to HLA class II-bearing cells in a sample and therefore satisfy the metes and bounds of the claims. Claim 12 recites the limitation that the peptides are in an antigenic composition further comprising a “pharmaceutically acceptable carrier.” Stevenson teaches that after incubation of the HLA class II antigenic material with the immobilized rat antibodies, the plates were washed (paragraph bridging pages 188-189 in particular). The wash buffer used by Stevenson is a carbonate buffer as evidenced by Tutt (Tutt, page 3058, column 2 in particular). Carbonate buffer is a water-based buffer and the water constitutes a “pharmaceutically acceptable carrier.” The prior art teaching anticipates the claimed invention. The composition clearly constitutes an “antigenic composition” because the mouse anti-HLA class II antibodies are able to bind to the immobilized HLA class II material (Figure 1 in particular).

Stevenson does not teach formulation of the peptide with an adjuvant.

Campbell teaches that “[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)” (page 29, section “Basic research” in particular). Harlow teaches that any substance that can elicit a humoral response can be used to prepare mAbs and that mAbs are powerful reagents for the testing for the presence of a desired epitope. Harlow teaches standard methods for formulating an antigen with adjuvant and methods for immunizing animals for the production of polyclonal and monoclonal antibodies (pages 72-77, 92-97, 128-135 and 141-157 in particular) as well as the types of antigens to which such antibodies can be made including proteins, peptides, and carbohydrates (pages 153-154 in particular).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make antibodies specific for HLA class II peptides for basic research. One would have been motivated, with a reasonable expectation of success, to generate mAbs to the peptides based on the fact that it is a conventional practice in the art to do so for further study, characterization and identification of a specific peptide and because of the role of HLA class II in the immune system.

Claim 17 is included because it is irrelevant to the claimed composition as to whether the HLA class II molecule was from a tumor cell or a normal APC.

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Conclusion

5. Claims 1, 3 and 4 are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571)272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
March 28, 2008

/David A Saunders/
Primary Examiner, Art Unit 1644